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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,451

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Mark Chandler

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EXAMINER

CLOW, LORI A

ART UNIT

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12/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,451	Applicant(s) CHANDLER ET AL.	
	Examiner LORI A. CLOW	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election without traverse of Group II, claims 11-38 in the reply filed on 5 October 2009 is acknowledged.

Claims 11-38 are currently pending and examined herein. Claims 1-10 have been cancelled.

Priority

The instant application is a divisional of US Application 09/662,790, filed 15 September 2000, which claims benefit to provisional 60/153,941, filed 15 September 1999 and to 60/227,516, filed 24 August 2000. It is noted that in the parent case (09/662,790) priority to 60/153,941, filed 15 September 1999 was denied because the '941 application fails to provide adequate written description to support the MAP Test Panel. Priority is denied in the instant application for the same reason. Further, provisional application 60/227,516, filed 24 August 2000, fails to provide adequate written description for the MAP Test Panel. Therefore, the effective filing date of the instant application is the filing date of parent case 09/662,790 (15 September 2000).

Information Disclosure Statement

The Information Disclosure Statement filed 29 September 2004 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

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Drawings

No Drawings have been submitted.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, please see page 15, lines 26-33 and page 16, lines 1-6; line 11, line 15, and line 17. Applicant is requested to remove all instances of hyperlinks in the Specification.

Claim Objections

Claim 11 is objected to because of the following informalities: Claim 11, step (f) recites, “from at least 25 about 1,000 subjects”. It appears as if a word is missing from the phrase. Please correct to read, “from at least 25 **to** about 1,000 subjects”.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 11 and those claims dependent therefrom recite, “harboring at least one reagent designed to interact selectively, if not specifically, with, and to generate biochemical data...”. It is unclear as to what “selectively” is intended to limit in the claim. Does it mean that the reagent interacts with one and only one analyte or something else? What are the metes and bounds of “selectively”? Clarification is requested.

Claim 11, and those claims dependent therefrom, recite, “a flow 20 analyzer”. It is unclear if this is a specific analyzer or if this is a typographical error. If it is a specific flow cytometer and it is trademarked, applicant is reminded of the rules for trademarks in claims as follows: As stated in MPEP 2173.05 (u), if a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). Further, a search of the Specification reveals no disclosure of a flow 20 analyzer. Clarification is requested.

Claim 22 recites, "some or all of the subjects are in relatively good health". It is unclear as to the metes and bounds of “relatively good health”. What constitutes “good health”? Clarification is requested.

Claim 23 recites, "some or all of the subjects are in relatively poor health". It is unclear as to the metes and bounds of “relatively poor health”. What constitutes “poor health”? Clarification is requested.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/14028 (Chandler et al.; PTO Form 1449 Reference), in view of WO 98/35609 (Campbell et al.; PTO Form 1449 Reference)

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The instant claims are drawn to a method of creating a database by providing samples from subjects, exposing a MAP Test Panel to at least a portion of one or more test samples, the MAP Panel comprising 20 or more subsets of microspheres, the microspheres of one subset being distinguishable from those of another subset with an agent designed to interact with an analyte, optionally adding supplemental reagents, passing the microspheres through a flow cytometer, compiling biochemical data into a database and repeating the steps for at least 25 to about 1,000 subjects.

In regard to claim 11, the Chandler et al. reference discloses a method for multiplexed diagnostic and genetic analysis of enzymes, DNA fragments, antibodies, and other biomolecules using beadsets and exposing them to a clinical sample and analyzing the beadsets by flow cytometry (abstract). The beadsets (panels) are prepared so that the beads within a subset differ in at least one distinguishing characteristic from beads in any other subset (page 7, lines 1-4). The beads within a subset can be coupled to a reactant that will specifically react with a given analyte. Different subsets can be coupled to different reactants (page 7, lines 15-19). Secondary reagents may be added, as well (page 7, line 29). Mixtures are run through a flow cytometer for analysis (page 8, line 1). Chandler et al. further teach the formulation of an assay database for which results from assayed bead sets may be stored (page 22, line 18 and page 25, lines 25-26).

In regard to claims 12 and 13, Chandler et al. teach that biological fluids, specifically blood, are used as test samples (page 35, lines 26 and 27).

In regard to claim 14, the Chandler et al. teach that the flow analyzer can process 2,000 beads per second, thus inherently the subsets would number 50 or more (page 22, line 6).

Further, Chandler et al. state that the number is relatively unimportant, as long as the sufficient

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numbers are used for good statistical characterization of the subset's parameters (page 23, lines 4-6).

In regard to claim 15, Chandler et al. teach the unique fluorescent identifiers for subsets of microspheres (page 30, lines 2-22).

In regard to claim 16, Chandler et al. teach reagents comprising antigens, for example, at page 35, lines 5-11.

In regard to claims 17 and 18, Chandler et al. teach analytes comprising antibodies (page 35, line 28).

In regard to claim 19, Chandler et al. teach washing the beads prior to flow analysis (page 36, lines 1-12).

In regard to claims 20 and 21, Chandler et al. teach determining genetic variations, for example, from PCR products (page 12, lines 1-17).

In regard to claim 22, Chandler et al. teach screening pregnant women, who would presumably be in relatively good health (page 39)

In regard to claim 23 and 24, Chandler et al. teach subject screening for pathogens, therefore the subjects would presumably be in poor health (page 40).

In regard to claim 25, subjects are assessed for pathological conditions et c. (page 17, lines 25-30).

In regard to claim 11, step (f), Chandler et al. does not specifically teach repeating all of the steps to compile at least 25 to 1,000 subjects. However, Campbell et al. teach a computer-based system to acquire biomarker data longitudinally from several thousand subjects (page 10, line 16..."no upper limit to the number of members included in the test population").

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In regard to the limitations as set forth in claims 26-38, Chandler et al. do not teach those specific embodiments. However, in regard to claims 26-28, Campbell et al. teach that subjects under go examination, histories, and answer surveys (page 20; page 21, line 11; page 35, line 18-19; page 37, lines 20-31).

In regard to claims 29-33, Campbell et al. teach that test samples may be obtained in a longitudinal manner and may be obtained monthly, annually, over a lifetime upon assessments (page 9, lines 23-31).

In regard to claims 34-37, Campbell et al. teach mixed model correlations and relationships of variables to one another (page 11, lines 23-26; page 12, lines 8-23; page 34, lines 1-9).

In regard to claim 38, Campbell et al. teach biochemical data sets that are unlimited in number of subjects (page 10, line 16).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the microsphere data sets of Chandler et al. with the biomarker analysis methods of Campbell et al. for the creation of a large dataset of subjects. One would have been motivated to do so because Campbell et al. state that any biological indicator can be used for comparing an individual's set of biomarker values with longitudinally-obtained database of sets of a large number of individual biomarker values for a large test population. Therefore, one would have had a reasonable expectation of success in using the biomarkers that are subsets of microspheres.

No claims are allowed.

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Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 16, 2009

/Lori A. Clow, Ph.D./

Primary Patent Examiner

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